DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 16, 2015

Dentsply International, Inc.
Ms. Helen Lewis
Director of Regulatory Affairs
221 West Philadelphia St., Suite 60W
York, Pennsylvania 17401

Re: K150535
Trade/Device Name: Cavitron Touch™ Ultrasonic Scaling System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: March 17, 2015
Received: March 19, 2015

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A

Indications for Use Statement

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K150535

Device Name: Cavitron Touch™ Ultrasonic Scaling System

Indications for Use:

Used for ultrasonic procedures:

- All general supra and subgingival scaling applications
- Periodontal debridement for all types of periodontal diseases

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DENTSPLY International
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SECTION 5. 510(k) SUMMARY
for
Cavitron Touch™ Ultrasonic Scaling System

1. Submitter Information**:**

DENTSPLY International Inc.
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17401

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 27 February 2015

2. Device Name:

- Proprietary Name: Cavitron Touch™ Ultrasonic Scaling System
- Classification Name: Ultrasonic Scaler
- CFR Number: 872.4850
- Device Class: II
- Product Code: ELC

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece	K052334	DENTSPLY International Inc.

4. Description of Device:

The Cavitron Touch™ Ultrasonic Scaling System is an ultrasonic scaling unit that is used in all general supra and subgingival scaling applications and periodontal debridement for all types of periodontal diseases. The Cavitron Touch™ Ultrasonic Scaling System includes a digital touch screen interface and Bluetooth technology. This device is equipped with the Tap-On™ Wireless Foot Pedal with Tap-On™ technology. Tap-On™ Wireless Foot Pedal was cleared under premarket notification K130862 in July 2013.

1. Indications for Use:
   Used for ultrasonic procedures:
   - All general supra and subgingival scaling applications
   - Periodontal debridement for all types of periodontal diseases

6. Substantial Equivalence:

Technological Characteristics

Proposed Device **Cavitron Touch™ Ultrasonic Scaling System**	**Predicate Device** **Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334)**
Indications for Use: Used for ultrasonic procedures • All general supra and subgingival scaling applications • Periodontal debridement for all types of periodontal diseases	**Indications for Use:** Used for ultrasonic procedures • All general supra and subgingival scaling applications • Periodontal debridement for all types of periodontal diseases • Endodontic procedures
Features: - All functions are touch screen activated, including the power setting, power presets, rinse, purge, scaling, and lock/unlock. All indicators are also visible on the touch screen, such as battery, service, water filter replacement, boost, manual, and Tap-On.	**Features:** - All functions are controlled through the analog power switch or a button located on the front cover. These functions include power setting, rinse, purge, and scaling. All indicators show on the information panel, including battery, service, boost, manual, and Tap-On.
- An adjustment collar on the handpiece offers the option of finer water control for precise and convenient adjustment of lavage on the handpiece to the preferred setting.	- An adjustment collar on the handpiece offers the option of finer water control for precise and convenient adjustment of lavage on the handpiece to the preferred setting.
The power range setting can be activated in two different ways. The clinician can touch the screen to move the circle up or down to the desired setting, or select one of the three power preset button options that are preset to the clinician's desired power setting. - The power range setting is defined	- The power range setting is controlled by a knob.

Proposed Device **Cavitron Touch™ Ultrasonic Scaling System**	**Predicate Device** **Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334)**
by lines as well as color on the touch screen.	
- Depressing the Tap-On™ Wireless Foot Pedal to the second positions initiates Temporary Boost to increase the stroke of the insert by at least 25% when at min power.	- Depressing the Tap-On™ Wireless Foot Pedal to the second position initiates Temporary Boost for a 10% increase in power.
- When the power boost feature is activated, the word "boost" will show in the "informational bubble".	- When the power boost feature is activated, the boost indicator will light up with a pink color signifying that an additional 10% of power is in use.
- The handpiece is autoclavable/ sterilizable as well as detachable from the unit.	- The handpiece is autoclavable/ sterilizable as well as detachable from the unit.
- The unit is equipped with a round, battery operated, ergonomically designed, Tap-On™ Wireless Foot Pedal. If preferred, the Tap-On™ Wireless Foot Pedal can be attached by wire. The Tap-On™ Wireless Foot Pedal contains two positions: one to activate the scaler and the other to activate the boost feature.	- The unit is equipped with a round, battery operated, ergonomically designed, Tap-On™ Wireless Foot Pedal. If preferred, the Tap-On™ Wireless Foot Pedal can be attached by wire. The Tap-On™ Wireless Foot Pedal contains two positions: one to activate the scaler and the other to activate the boost feature.
- The battery indicator is always present on the screen. This allows the clinician to see how much battery life remains in the wireless Tap-On™ Wireless Foot Pedal before it must be recharged.	- A battery symbol will light up on the interface indicating that the battery in the Tap-On™ Wireless Foot Pedal needs to be replaced.
- The Tap-On™ Wireless Foot Pedal allows the clinician to use a single Tap-On™ the foot pedal to activate or deactivate continuous scaling. This permits the clinician to rest their foot during the procedure.	- The Tap-On™ Wireless Foot Pedal allows the clinician to use a single Tap-On™ the Tap-On™ Wireless Foot Pedal to activate or deactivate continuous scaling. This permits the clinician to rest their foot during the procedure.
- When the Tap-On™ Wireless Foot Pedal technology is engaged, the word "Tap-On" will appear in the "Informational Bubble".	

Proposed Device **Cavitron Touch™ Ultrasonic Scaling System**	**Predicate Device** **Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334)**
- To deactivate the Tap-On™ technology, the clinician must push the Tap-On™ button located on the interface. - The Purge cycle allows the clinician to purge the water lines by pressing the Purge button located on the touch screen. The Purge screen appears and displays the cycle countdown of 120 seconds or 2 minutes. After the 2 minute cycle is complete, the screen will return to the Scale screen. - The Rinse mode allows the clinician to rinse the area for the patient where needed without the tip moving. Pressing the Rinse button on the touch screen will bring up the Rinse screen. The tip will not move and the system will only rinse. Once finished with the Rinse mode, the clinician can press the Scale button on the touch screen to return to the Scale screen. - Sustained Performance System (SPS), similar to cruise control, will adjust the power when needed. - The flat surfaces of the device make it easy to clean to minimize the risk of cross-contamination. A disposable barrier will be provided to cover the screen. - When the water filter needs to be replaced, the Water Filter Indicator Light will light up on the touch screen. - The device is internally equipped with a water solenoid, which is where the water comes into the unit and continues to flow to the	- To deactivate the Tap-On™ technology, the clinician must press the Purge and Turbo simultaneously for a few seconds. - The Purge cycle allows the clinician to purge the water lines. A single push button is used to activate the 2 minute purge cycle. The button will stay illuminated until the cycle is completed. - The Rinse mode allows the clinician to rinse the area for the patient where needed without the tip moving. To initiate the Rinse mode, the clinician will turn the knob to the Rinse icon until they feel it click. Once the knob is properly in place, the tip will not move and the system will only rinse. To return to scaling, turn the knob off of the Rinse icon. - Sustained Performance System (SPS), similar to cruise control, will adjust the power when needed. - This device is easy to clean. To clean underneath the knob, simply remove the knob from the device. - The device is internally equipped with a water solenoid, which is where the water comes into the unit and continues to flow to the

Proposed Device **Cavitron Touch™ Ultrasonic Scaling System**	**Predicate Device** **Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334)**
handpiece.	handpiece.
- When the device needs to be serviced, the Service Indicator Light will appear on the touch screen. The 4 pre-programmed service indicators are: missing handpiece, unit over temperature, filter replacement, and battery status.	- When the device needs to be serviced, the Service Indicator Light will illuminate on the interface.
- This device has Bluetooth wireless technology capabilities.	- This device has radio frequency (RF) wireless technology capabilities.
- The half-life of a white LED backlight, which is used in the LCD Screen of the device, is approximately 20,000 hours.	
- The water range setting indicator goes from 1 – 6 with half markings.	- The water range setting indicator goes from 1 – 6 with half markings.
- It is recommended the plastic water filter be replaced once a month.	- It is recommended the plastic water filter be replaced once a month
- The system operates over a frequency range of 28.5 – 31.5 kHz.	- The system operates over a frequency range of 28.5 – 31.5 kHz.
- The input voltage of the scaler is 100 – 240 VAC, 50 to 60 Hz.	- The input voltage of the scaler is 100 – 240 VAC, 50 to 60 Hz.
- The system provides a means for control of power (tip stroke) and lavage flow rates.	- The system provides a means for control of power (tip stroke) and lavage flow rates.

The Cavitron Touch™ Ultrasonic Scaling System is an ultrasonic scaler which is intended to be used for all general supra and subgingival scaling applications as well as periodontal debridement for all types of periodontal diseases. The Cavitron Touch™ Ultrasonic Scaling System has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece cleared under premarket notification K052334. The differences in the table above do not raise any new or different types of questions of safety and effectiveness.

7. Non-Clinical Performance Data.

Performance testing focused on verification of design, ultrasonic scaling performance, and function of the Cavitron Touch® Ultrasonic Scaler. Below is a summary of the testing performed:

- AAMI ANSI ES 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance (2005; reapproved 2012)
- IEC 60601-1-2 Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility (2007)
- FDA - Guidelines for the Content of Premarket Submissions for Software Contained in Medical Devices- Software Validation
- Internal specification and testing for handpiece operation, including lavage control
- Internal specification and testing for autocycle operation
- Internal specification and testing for touch screen and user interface functionality
- Internal specification and testing for radio frequency distance for Tap-On™ Wireless Foot Pedal (K130862)

The results of these performance tests support the substantial equivalence of the proposed Cavitron Touch™ Ultrasonic Scaling System with the predicate Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334).

New biocompatibility testing was not required to support the substantial equivalence between the proposed Cavitron Touch™ Ultrasonic Scaling System and the predicate device, Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334). Biocompatibility testing was submitted with the predicate device, Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece and cleared under premarket notification K052334. The Cavitron® Steri-Mate™ Sterilizable Handpiece was previously cleared as Jet-Mate™ Sterilizable Handpiece under premarket notification K023697.

1. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the Cavitron Touch™ Ultrasonic Scaling System.

2. Conclusion Regarding Substantial Equivalence

The Cavitron Touch™ Ultrasonic Scaling System is an ultrasonic scaler which is intended to be used for all general supra and subgingival scaling applications as well as periodontal debridement for all types of periodontal diseases. The Cavitron Touch™ Ultrasonic Scaling System has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece cleared under premarket notification K052334. Testing to verify the performance of the Cavitron Touch™ Ultrasonic Scaling System shows that the key features and performance of the Cavitron Touch™ Ultrasonic Scaling System are substantially equivalent to the predicate device, Cavitron® RF Ultrasonic Scaler System with Sterimate Handpiece (K052334).